

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATERA, INC.

Plaintiff,

V.

BIO-REFERENCE
LABORATORIES, INC.

Defendant.

Civil Action No. _____

COMPLAINT

Jury Trial Demanded

Plaintiff Natera, Inc. (“Natera”), by its attorneys Jenner & Block LLP, states for its complaint for breach of contract and misappropriation of trade secrets against Defendant Bio-Reference Laboratories, Inc. (“Bio-Reference”) as follows:

SUMMARY OF ACTION

1. Natera, a genetic testing company that specializes in genetic screening including noninvasive prenatal testing (“NIPT”), brings this Complaint against Bio-Reference, the largest outside distributor of Natera’s flagship Panorama Test, to prevent Bio-Reference from launching a competing NIPT product developed by a third party. Natera learned this week, definitively only yesterday, that Bio-Reference plans a nationwide launch on Monday, December 12 of a third-party NIPT test called ClariTest, which will compete with Natera’s Panorama test. Bio-Reference’s promotional materials for that marketing campaign violate several express marketing restrictions in the Amended and Restated Licensing and Joint Development Agreement between Natera and Bio-Reference (the “Licensing Agreement”): The materials

discuss ClariTest more prominently than the Panorama Test; they make comparisons that are not supported by peer-reviewed publications; and they disparage the Panorama Test. To make matters worse, Bio-Reference's launch of ClariTest will abuse confidential information that Natera provided Bio-Reference only for the purpose of marketing the Panorama Test, and that Natera would never have provided Bio-Reference if Bio-Reference had truthfully disclosed that it was already planning a broad launch of a competitor's product. To prevent and remedy this breach of contract and misappropriation of trade secrets, Natera seeks a Preliminary Injunction and Temporary Restraining Order and damages, as described below.

PARTIES

2. Plaintiff Natera is a Delaware corporation that develops biotechnology testing services, including NIPT. Its principal place of business is at 201 Industrial Road, Suite 410, San Carlos, CA 94070.

3. Defendant Bio-Reference is a New Jersey corporation that distributes Natera's and other companies' NIPT (and other) products to hospitals, clinics, and doctors. Its principal place of business at 481 Edward H. Ross Drive, Elmwood Park, NJ 07407.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a). There is complete diversity of citizenship between the parties, as Natera is a citizen of Delaware and California and Bio-Reference is a citizen of New Jersey. The amount in controversy is in excess of the sum or value of \$75,000, exclusive of interest and costs.

5. Venue is proper in this Court under 28 U.S.C. § 1391(b) because a substantial portion of the events giving rise to Natera's claims occurred in the state of New York. If venue is not appropriate under 28 U.S.C. § 1391(b), venue is appropriate under 28 U.S.C. § 1391(c)

because the Licensing Agreement provides at Section 9.6: “All legal proceedings relating to this agreement shall take place in the federal and state courts located in New York, New York, borough of Manhattan. Each party consents to the exercise of jurisdiction over it by said courts.”

FACTUAL ALLEGATIONS

The Parties

6. Natera is a leader in the reproductive testing industry, offering various solutions for NIPT, genetic-carrier screening, preimplantation genetic testing, and miscarriage testing.

7. One of Natera’s market-leading products is Panorama, which is an NIPT that can reveal a baby’s risk for genetic disorders as early as nine weeks after pregnancy. Using highly proprietary technology developed by Natera, Panorama analyzes a baby’s (placental) DNA through a simple blood draw from the mother’s arm.

8. The Panorama Test provides families with a full panel of options by screening for the most common genetic conditions, including conditions such as Down syndrome that are caused by extra or missing copies of a specific chromosome as well as conditions such as microdeletions that occur when a chromosome is missing a small piece of genetic information.

9. Bio-Reference is one of the largest full-service clinical diagnostic laboratories in the United States, providing testing and related services to physicians, clinics, and hospitals. It is the largest outside distributor of Natera’s products.

The Licensing Agreement

10. In or about April 2015, Natera and Bio-Reference entered into the Licensing Agreement (which restated an earlier agreement effective as of February 7, 2013). In the Licensing Agreement, Natera and Bio-Reference broadly agreed that Bio-Reference would continue to distribute Natera’s Panorama Test; Natera granted Bio-Reference a license to use

certain intellectual property to develop its own NIPT “Licensed Test”; and Bio-Reference was not prevented from distributing NIPT tests developed by third parties so long as it complied with certain express limitations on marketing and promoting third-party NIPT tests rather than the Panorama Test or the Licensed Test (collectively, the “Tests”).

11. More specifically, during the “Initial Phase” of the agreement, Bio-Reference had the right to market, sell, and collect specimens for Panorama Tests. Licensing Agreement Section 1.3(a). Bio-Reference would then deliver the specimens to a Natera laboratory, where the Panorama test would be performed. *Id.* Natera, in turn, would provide Bio-Reference with the test result reports, which would then be delivered to the customer.

12. Also during the Initial Phase, Bio-Reference had the right to develop a “Licensed Test,” which is an NIPT test that would employ certain licensed technology from Natera. Licensing Agreement Section 1.2(ee)). Specifically, Natera “grant[ed] a license to the requisite Natera Intellectual Property rights on a non-exclusive basis to [Bio-Reference] and its employees in order to allow [Bio-Reference] and its employees to develop, set up, operate, perform, market, sell and offer for sale the Licensed Test in the United States.” Licensing Agreement Section 1.2(ee)).

13. Crucially, the License Agreement restricts Bio-Reference’s ability to market NIPT tests developed by third parties, that is, tests other than the Panorama Test or the Licensed Test. In particular, the License Agreement provides:

[Bio-Reference] shall actively promote the Panorama Test during the Initial Phase, shall actively promote the Licensed Test during the LDT Phase, and shall not disparage these Tests [which includes the Panorama Test and the Licensed Test]. In any promotional messaging or materials, the Tests shall be discussed no less prominently than any third party NIPT Test and any comparison of a Test to a third party NIPT Test or claims about a third party NIPT Test shall only be based on data from peer-reviewed publications.

Licensing Agreement Section 4.3.

14. Section 4.3 thus contains at least four separate restrictions: (1) Bio-Reference must actively promote the Tests; (2) Bio-Reference cannot disparage either of the Tests that use Natera technology; (3) Bio-Reference cannot discuss third party NIPT tests more prominently than either of the Tests using Natera technology; and (4) any comparisons or claims must be based on data from peer-reviewed publications.

15. The Licensing Agreement imposes additional restrictions on each party's use and disclosure of the other's confidential information. The Licensing Agreement provides:

Each Party shall hold in confidence (i) such information, other than Background Technology, as it receives from the other Party and which the disclosing Party designates as being confidential or which a reasonable person would believe is confidential and would know to treat as confidential (collectively, "Confidential Information"), and (ii) such information as it jointly develops with the other Party and which is not publicly disclosed by agreement of the Parties. The provisions of the Non-Disclosure Agreement dated November 22, 2011 between NATERA and BRLI shall apply to the extent consistent with this Agreement.

Licensing Agreement Section 5.3 ("Confidentiality").

16. The parties further agreed that, were the Licensing Agreement's confidentiality restrictions to be violated, the non-breaching party would be entitled to equitable relief without a requirement to post bond. Under the Licensing Agreement:

Each Party acknowledges that a breach or threatened breach of Section 5.1, Section 5.2 or Section 5.3 would give rise to irreparable harm to the other Party (the "Non-Breaching Party"), for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by such Party of any such obligations, the Non-Breaching Party shall, in addition to any and all other rights and remedies that may be available to it in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction (without any requirement to post bond).

Licensing Agreement Section 5.4 ("Specific Performance").

17. The Licensing Agreement also provides that for certain types of breaches, “in no event shall consequential, incidental or punitive damages be applicable or awarded with respect to any dispute that may arise between the parties in connection with this agreement”; and (b) each party’s “total cumulative liability in connection with this agreement” is capped at the greater of \$5 million or the amounts due under the Licensing Agreement and its preceding agreement over the 12-month period preceding the claim. Licensing Agreement Section 9.13.

Bio-Reference Plans a Marketing Campaign

18. Beginning sometime at least as early as the summer of 2016, Bio-Reference planned a campaign to promote a third-party NIPT Test, the so-called “ClariTest.” ClariTest is a competing NIPT being developed chiefly by Illumina, Inc., a direct competitor to Natera through its Verinata division.

19. Simultaneously, Bio-Reference entered into further discussions with Natera to induce Natera to provide additional confidential information that Natera provided under the Licensing Agreement to promote the Panorama Test, but which Bio-Reference secretly intended to use to promote ClariTest.

20. During the course of those discussions, Bio-Reference informed Natera that it was planning to provide an NIPT from Illumina (what is now known as the ClariTest) to a single customer, when in fact Bio-Reference was planning a nationwide promotional launch of ClariTest to all its customers.

21. Had Natera known that Bio-Reference was planning a nationwide launch, let alone a nationwide launch through a marketing plan that would violate the terms of the Licensing Agreement, Natera would not have provided any additional confidential information to Bio-Reference.

22. In particular, starting in or about July 2016, Natera provided Bio-Reference with confidential information concerning costs of goods sold, various methods that Natera had developed to reduce the costs of its tests, proposals to improve billing and insurance reimbursement procedures, appeal denials, and other back end management issues.

23. Worse yet, Natera provided Bio-Reference with information concerning the best strategies for selling the Tests against a Illumina's NIPT—the very competing test, which, as described below, Bio-Reference plans to imminently promote against Panorama in breach of its contractual obligations.

24. During these discussions, Natera also described to Bio-Reference the biotechnology intellectual property underlying the Panorama Test and Natera's positions with respect to competitive biotechnology. These biotechnological insights reflect Natera's trade secrets and intellectual property.

25. In reliance upon its partnership with Bio-Reference, Natera also shared confidential information with Bio-Reference unrelated to NIPT. Based on Bio-Reference's assertions that it might partner with Natera on matters related to cancer diagnostic products, Natera shared product information about its cancer diagnostic product pipeline and business information about cancer diagnostic product opportunities in specific markets.

26. Bio-Reference induced Natera to share this confidential information through knowing deceit. Bio-Reference sought, and obtained, the information from Natera based upon covenants in the Licensing Agreement that Bio-Reference already intended to abandon. Worse, when Natera asked Bio-Reference about its marketing plans for ClariTest, Bio-Reference lied. By using false premises and express dishonesty to induce Natera to share its trade secrets with, in effect, a competitor, Bio-Reference converted Natera's intellectual property.

27. Additionally, in light of all the confidential information it has received from Natera, including specifically the confidential information it has received concerning the Tests and NIPTs generally, it is inevitable that Bio-Reference's planned launch of ClariTest will involve the use of Natera's confidential information. Further, ClariTest is not Bio-Reference's own product, but Illumina's. It is inevitable that Natera confidential information, including trade secrets, known to Bio-Reference, will become known to Illumina during the course of the ClariTest launch and/or a subsequent partnership between Bio-Reference and Illumina. Such usage and/or dissemination is a tortious misappropriation of Natera's confidential information, as well as a plain breach of the confidentiality provisions contained in Section 5.3 of the Licensing Agreement.

Bio-Reference's Imminent Breach

28. Yesterday, on December 8, 2016, Natera definitively learned that Bio-Reference is planning to launch a nationwide marketing campaign for ClariTest, and not just provide ClariTest to a single customer, as was previously disclosed. The launch is scheduled for Monday, December 12, 2016. This campaign will be at the expense, and involve the disparagement, of Panorama. It will necessarily trade on Natera's misappropriated confidential information and trade secrets.

29. As described below, Bio-Reference has produced at least two sets of promotional materials for ClariTest.

Promotional Materials Geared Towards Medical Professionals

30. Bio-Reference has a promotional brochure called "ClariTest: Non-Invasive Prenatal Testing." On information and belief, this marketing material is intended for medical professionals such as obstetricians and gynecologists.

31. This brochure does not mention the Panorama Test by name. That omission is a clear breach of Section 4.3 of the Licensing Agreement, which provides that “the Tests shall be discussed no less prominently than any third party NIPT test.”

32. Moreover, this brochure contains various claims and comparisons that are not supported by peer-reviewed publications and/or that implicitly disparage the Panorama Test, also in violation of Section 4.3. For example:

- a. The brochure bears the headings “Reliable Results the First Time: Brings Clarity to Your Patients” and “Quick, Accurate Reporting.” These statements are not supported by any data or any citation to peer-reviewed studies. Additionally, these statements indirectly disparage Natera’s Panorama Test because, in accordance with the American Congress of Obstetricians and Gynecologists (“ACOG”) guidelines, the Panorama Test deliberately does not always give results “the first time”; rather, the Panorama Test does not yield results when the patient’s sample is below the fetal fraction percentage deemed to be appropriate for testing. The ClariTest, by contrast, uniformly returns a result “the first time,” but to do so it ignores the ACOG guidelines and thus produces less accurate results.
- b. The brochure states, “ClariTest Screens for Common Microdeletions.” On information and belief, ClariTest’s sensitivity to microdeletions is only 10%-25%, which is not sufficient to meet the industry standard for screening. This is in contrast to Panorama’s sensitivity of greater than 95% for select microdeletions. The brochure’s failure to contrast the superior performance of Panorama to

ClariTest and display Panorama's sensitivity no less prominently is a violation of the contract.

- c. The brochure also contains a table purporting to show ClariTest's performance testing for four common chromosomal aneuploidies. In support of this data, the brochure makes reference to a white paper issued by a wholly-owned subsidiary of Illumina. On information and belief, this white paper is not a peer-reviewed publication.
- d. Further, Bio-Reference's report that ClariTest correctly identified 90/90 true positive samples for T21 (Down syndrome) in a performance test is inconsistent with the findings of peer-reviewed research.
- e. The brochure also says that "Other NIPT technologies result in a greater rate of no-calls (test failures), causing patient anxiety, and often resulting in unnecessary invasive procedures," and that "Low Test Failure Rates Mean: Reduced Patient Anxiety, Less Repeat Testing, and Fewer Unnecessary Invasive Procedures." These comparisons and claims are not supported by any citation to peer-reviewed publications, and upon information and belief, there is no such support for these statements. These comparisons also implicitly disparage the Panorama Test, as explained in (b), above.
- f. The brochure contains a table purporting to calculate the "potential number of unaffected pregnancies subject to an invasive procedure" for ClariTest and other NIPT methods, including the method used by Panorama. This calculation is speculative and is not supported by any peer-reviewed publication.

- g. Further, the same table purports to show that ClariTest is more accurate at testing for T21 (Down syndrome) than Panorama. On information and belief, the brochure's representations are based on outlier literature, if anything at all. A broad selection of peer reviewed studies show that Panorama shows superior performance at testing for T21, and far superior performance at testing for T18 and T13—a comparison the brochure does not make.

33. Yet other statements violate the Licensing Agreement's prohibition on disparaging Panorama, and Bio-Reference's commitment to promote it. For example:

- a. The promotional brochure bears the headings "The Right Choice for Non-Invasive Prenatal Testing" and "A Superior NIPT Available to a Broader Patient Population." Moreover, the brochure says that "ClariTest from GenPath represents a major advance in prenatal testing, harnessing the power of massively parallel sequencing to screen for fetal chromosomal abnormalities." These statements are disparaging by implication. At a minimum, they do not promote the Panorama test.
- b. Additionally, as recited above, the brochure contains speculative calculations about patients "potentially subject to an invasive procedure." The selective citation to research literature, the use of unsupported calculations and unexplained assumptions, and the presentation of "potential" numbers amount to a misleading portrait that ClariTest is superior to the Panorama test. Far from promoting the Panorama test, these tables disparage the Panorama test.

Promotional Materials Geared Towards Patients

34. A promotional brochure intended for patients, which begins "Congratulations on

your pregnancy!,” breaches Section 4.3 of the Licensing Agreement in the same ways.

35. First, the brochure discusses the ClariTest at length but never once mentions the Panorama Test by name. As a result, this brochure violates Section 4.3 of the License Agreement, which provides that, for any promotional messaging or materials, “the Tests shall be discussed no less prominently than any third party NIPT.”

36. Second and third, several of the claims in the brochure violate Section 4.3’s requirements not to disparage the Panorama Test, and/or that claims or comparisons made in promotion materials be “based on data from peer-reviewed publications.” As just two examples:

- a. This promotional brochure claims that ClariTest provides readers “The Reliability You Seek,” stating, “Today there are a number of genetic testing options available for expectant women and their healthcare providers. ClariTest has lower false positive rates and higher detection rates compared to other screening tests, and therefore, provides more accurate results regarding the risk for certain chromosome abnormalities. While detection rates are high and false positive rates are low, it is important to remember that ClariTest is still a screening test.” Natera believes that these statements are not based on data from peer-reviewed publications, and the brochure does not provide any basis to believe they are.
- b. The brochure also claims that ClariTest provides more accurate results than other screening tests. That claim disparages the Panorama Test and is factually inaccurate.

COUNT I

BREACH OF CONTRACT

37. Natera repeats and realleges paragraphs 1 through 36 as if fully set forth herein.

38. The Licensing Agreement is a binding and enforceable contract.

39. Natera has performed all requisite conditions, covenants, and promises under the Licensing Agreement.

40. As alleged herein, Bio-Reference has intentionally and materially breached its express contractual obligations under the Licensing Agreement.

41. In particular, in breach of Section 4.3 of the Licensing Agreement, Bio-Reference's third-party marketing campaign (1) will disparage the Panorama and License Tests, (2) discusses a third-party NIPT Test more prominently than the Panorama and License Tests, and (3) makes comparisons or claims based on data that is not from peer-reviewed publications.

42. Additionally, in breach of Section 5.3 of the Licensing Agreement, Bio-Reference's third-party marketing campaign will inevitably misuse or disseminate Natera's confidential information. Under Section 5.4 of the Licensing Agreement, such breaches inflict irreparable harm and are properly enjoined.

43. As a result of Bio-Reference's breaches, Natera has suffered or will imminently suffer damages.

COUNT II

MISAPPROPRIATION OF TRADE SECRETS

44. Natera repeats and realleges paragraphs 1 through 36 as if fully set forth herein.

45. Natera possessed trade secrets, which are defined as any formula, pattern, device, or compilation of information which is used in one's business, and which gives the owner an opportunity to obtain an advantage over competitors who do not know or use it.

46. Natera's trade secrets at issues include information concerning COGS (cost of goods sold), reimbursement maximization, and, most directly relevant, marketing strategies with respect to third-party NITP Tests.

47. Bio-Reference has already used and/or plans to use Natera's trade secrets in the ClariTest launch in breach of the Licensing Agreement, confidential relationship or duty, or as a result of discovery by improper means.

48. As a result of Bio-Reference's misappropriation of trade secrets, Natera has suffered or will imminently suffer damages.

COUNT III

THEFT OF CONFIDENTIAL INFORMATION

49. Natera repeats and realleges paragraphs 1 through 36 as if fully set forth herein.

50. Natera possessed confidential information, including information concerning COGS (cost of goods sold), reimbursement maximization, and, most directly relevant, marketing strategies with respect to third-party NITP Tests.

51. Bio-Reference obtained Natera's confidential information through knowing deceit. This included leveraging Natera's reliance on covenants in the Licensing Agreement that Bio-Reference intended to breach, and outright lies about Bio-Reference's marketing plans for ClariTest.

52. As a result of Bio-Reference's conversion of Natera's confidential information, Natera has suffered or will imminently suffer damages.

PRAYER FOR RELIEF

WHEREFORE, Natera respectfully requests that the Court enter an Order:

- A. Temporarily, preliminarily and/or permanently enjoining Bio-Reference from engaging in its anticipated marketing campaign of ClariTest;
- B. Temporarily, preliminarily and/or permanently enjoining Bio-Reference from marketing any NIPTs in violation of the Licensing Agreement;
- C. Temporarily, preliminarily and/or permanently enjoining Bio-Reference from misappropriating Natera's trade secrets or other confidential information;
- D. Awarding actual damages that Natera is entitled to recover as a result of Bio-Reference's breaches of the Licensing Agreement and misappropriation of Natera's trade secrets;
- E. Awarding punitive damages;
- F. Awarding Natera the costs of these proceedings;
- G. Awarding Natera its reasonable attorneys' fees and costs; and
- H. All other relief as this Court deems appropriate.

Dated: December 9, 2016

Respectfully submitted,

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